

Applicant: Thompson, P.
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Rejections under 35 U.S.C. §102(a)/(e)

The Examiner has rejected claim 19 under 35 U.S.C. §102(a)/(e) as being anticipated by Myers et al. (WO 95/05132 and U.S. Patent No. 5,700,285). More specifically, the Examiner states:

Myers et al discloses a braided stent (see Figure 9) intimately bound (see Figure 8) to a biaxially expanded PTFE graft; see the whole document. For this reason, the claim language is fully met because the stent and graft would inherently expand and contract together such that the expansion ratios thereof would be virtually the same; in other words, the expansion ratios [ratios] would [be] less than 25% as claimed.

In further response to Applicants arguments, the Examiner alleges that internodal [distance] shortening is inherent in Myers. Specifically, the Examiner states that Myers has biaxially and multiaxially expanded films of PTFE intimately bound with a stent. The stent is braided so it will shorten upon radial expansion, and when this happens, since the PTFE is intimately bound thereto, and since the PTFE is multiaxially expanded, the PTFE fibrils between the nodes will shorten.

Applicant respectfully disagrees.

In order to establish an inherent characteristic in a document it is necessary for the Examiner to provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d, 1461, 1464, (BD. Pat. Att. & Inter. 1990). Furthermore, extrinsic evidence presented to establish inherency must make clear that the missing descriptive matter is necessarily present in the same described reference and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In Re Robinson*, 169 S.3d 743, 745; 49 USPQ2d

1949, 1950-51 (Sub. Cir. 1999).

With reference to both U.S. Patent No. 5,700,285 and WO 95/05132, it is apparent that not only are these qualities not inherent in the disclosure, but rather the disclosure teaches away from the properties which the Examiner attributes to the intraluminal stent/graft in Myers.

The stent/graft in Myers is assembled with the stent in an expanded diameter. The diameter of the intraluminal stent/graft is then reduced to a delivery profile (see examples 1-3 of both documents). Contrary to the Examiner's assertion however, the ePTFE is not necessarily "intimately" bound with the stent, and there is no reason to believe the ePTFE cover will behave as the Examiner has postulated. Based on the non-elastic nature of ePTFE, there is in fact, reason to believe ePTFE will exhibit other characteristics.

ePTFE is not an elastomeric substrate, and typically with an ePTFE stent/graft, the ePTFE will not be intimately bound with the stent. In the case of an ePTFE stent/graft assembled in an expanded condition, a reduction in diameter typically results in folds, pillowing, and/or slack in the ePTFE. This pillowing or slack in the ePTFE of prior art stent/grafts is specifically referenced in the present invention, and the present application was designed in order to prevent such slack from occurring (See Specification, page 11, lines 3-13).

It is therefore submitted by Applicant that the properties which the Examiner attributes are inherent to expanded polytetrafluoroalkylene would in fact, not be present in the stent/graft in Myers, and that this presumption has been rebutted by Applicant.

The Examiner further asserts that Applicant's previous arguments regarding the gradient between internodule distance after radial expansion is irrelevant because the claim limitation is not claimed. Applicant respectfully disagrees. Claim 19 clearly claims a "shortening of average longitudinal inter-nodule distance upon radial expansion from a first average longitudinal inter-nodule distance to a second average longitudinal inter-nodule distance." The claimed difference in average longitudinal internodule distance is certainly a gradient and the argument is therefore

deemed relevant as there is no such gradient in Myers.

Furthermore, because Myers is assembled with the stent in an expanded state, and thus its first state, and the ePTFE (stent/graft) not being expanded beyond this expanded (first) state, the apparatus of Myers does not therefore meet the limitations of claim 19 of the present invention. More specifically, there is no second average longitudinal inter-nodule distance which is less than the first average distance upon radial expansion because there is no radial expansion from the first expanded state of assembly. In fact, the ePTFE on the intraluminal stent/graft is Myers is merely reduced by folding, pillowing, and slack when the intraluminal stent/graft is brought to its reduced delivery diameter.

The Examiner has therefore failed to show where Myers discloses different longitudinal internodule distance in the radially expanded and contracted state. Moreover, the Examiner has provided no support or explanation as to why such internodule distance gradient would be inherent. Applicant has further rebutted that such an internodule distance would be inherent.

Myers therefore does not disclose the present invention as claimed and withdrawal of the rejection under 35 U.S.C. §102 (a)/(e) based upon Myers is respectfully solicited.

Rejections Under 35 U.S.C. §103

The Examiner has also rejected claim 20 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,749,880 to Banas et al. in view of U.S. Patent No. 4,954,126 to Wallsten. More specifically, the Examiner states:

Banas et al discloses many stent types which can be bonded to uniaxially expanded PTFE with no nodules (only nodes, see Figure 18A-19B). However, Banas fails to specifically disclose using a braided stent as claimed. Wallsten, however, teaches that it was known to the art to make braided self-expanding stents. Hence, it is the Examiner's position that it would have been obvious to use a braided self-expanding stent, as taught by Wallsten, for the same reasons that Wallsten desires the same and so that self-expansion

and even distribution of pressure can be brought to the Banas et al device.

The Examiner further states in response to Applicant argument on pages 4-5 of the Office Action that, "Nodes and nodules have different meaning in the art. Nodes are merely regions of solid PTFE while nodules are circularly-shaped islands of PTFE." Applicant is unaware of any such distinction and invites the Examiner to give evidence of such an assertion. The Examiner seems to indicate that a nodule is only present in the biaxially oriented ePTFE structure. It is Applicant's understanding that a nodule is the equivalent of a node in the ePTFE node fibril structure and that a nodule may in fact be present in a uniaxially expanded PTFE structure. This is evident in the specification where Applicant defines the average internodual distance of both uniaxially and biaxially expanded PTFE structure on page 7, lines 25-30.

A close review of Figures 18a to 19b of Banas reveals ePTFE structure comprised of nodules, or node, connected by fibrils in the typical construction of ePTFE. Each of Figures 18a through 19b, and in fact, the entire specification and claims, discusses ePTFE with this node [or nodule] and fibril relationship.

Furthermore, at column 22, lines 61-67, the specification states, "From each of the Figures 18a -20b it can be readily seen that when the stent graft is radially expanded, the ePTFE node-fibril microstructure undergoes little elongation in the axis of radial expansion while the bonded area of sintered ePTFE in the wall thickness remains integrally and monolithically bonded, and substantially without interlayer demarcation."

Applicant submits that the Examiner has therefore not established a *prima facie* case of obviousness under 35 U.S.C. §103(a). The Examiner has failed to make a *prima facie* showing of obviousness and neither reference discloses an ePTFE structure characterized by having substantially no nodules. There is further, no teaching or suggestion in any reference cited by the Examiner of any PTFE structure with substantially no nodules.

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It is respectfully submitted that the rejection based on 35 U.S.C. §103(a) is improper, and removal of the rejection is respectfully solicited.

For the reasons set forth, withdrawal of the rejections and favorably reconsideration is respectfully requested. Should the Examiner have any questions regarding this response or wish to discuss the matter in further detail, please contact the undersigned attorney.

Respectfully submitted,



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